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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------|------------------|
| 10/070,954 | 07/22/2002 | Stephen Arkinstall | ARKINSTALL=1 | 4903 |
| 1444 | 7590 | 06/21/2006 | EXAMINER | |
| BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303 | | | COLEMAN, BRENDA LIBBY | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1624 | |

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/070,954

Applicant(s)

ARKINSTALL ET AL.

Examiner

Brenda L. Coleman

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-41 are pending in the application.

This action is in response to applicant's amendment filed March 30, 2006.

Claims 1-3, 5, 9, 10, 13, 17-19 and 22 have been amended.

Response to Amendment

Applicant's arguments filed March 30, 2006 have been fully considered with the following effect:

1. With regards to the 35 U.S.C. § 112, first paragraph rejection of claims 13-20, 23-26, 32-34 and 37-41 labeled paragraph 3 maintained in the last office action, the applicants' arguments have been fully considered, however they were not found persuasive. The applicants' stated that Glicksman et al. provided by the applicant shows the correlation of the inhibition of the JNK pathway and the reduction of neuronal death degeneration *in vivo*. However, Glicksman states that while CEP-1347/KT7515-mediated motor neuronal survival *in vitro* was correlated with inhibition of JNK1, the relevance of this pathway to motor neuronal death *in vitro* or *in vivo* has not been demonstrated. Glicksman also states that to determine the role of CEP-1347/KT7515 intervention in signaling pathways that regulate neuronal death, we are currently investigating pathways resulting in JNK and *c-jun* activation and cell death in cultures enriched for motor neurons. Glicksman concludes that although the exact mechanism of action has yet to be understood, CEP-1347/KT7515 was effective in preventing motor neuronal death and degeneration *in vitro* and *in vivo*.

Claims 2, 3, 13-20, 23-26, 29-34 and 37-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record and stated above.

2. The applicant's amendments and arguments are sufficient to overcome the 35 USC § 112, second paragraph rejections of claims 3 and 5, labeled paragraph 2k) and n) maintained in the last office action, which are hereby **withdrawn**. However, with regards to the 35 USC § 112, second paragraph rejections of claims 13-20, 23-26, 32-34 and 37-41, labeled paragraph 2aa), the applicant's amendments and arguments have been fully considered, however they were not found persuasive.

aa) The applicants' stated that it is not necessary to know what diseases are affected by modulating the JNK pathway, as applicant has found that the compounds claimed herein are capable of modulating the JNK pathway, which has been shown to affect a great many diseases. However, claims 13-20, 23-26, 32-34 and 37-41 generically claims the method of treating a disorder responsive to the activity of modulation of JNK pathway. As stated in previous office actions the rejection of claims 13-20, 23-26, 32-34 and 37-41 were on the grounds that it is indefinite, in that it is not known which diseases are capable of being responsive to the activity of JNK. Weston et al., Current Opinion in Genetics and Development is speculative at best to the use of inhibitors of JNK signaling. Weston states that the JNK signaling pathway has been implicated in many

pathological conditions and that drugs that inhibit JNK signaling **may** therefore be therapeutically beneficial. Weston also states that many questions remain concerning the function of the JNK signaling pathway. Thus, the scope of diseases and/or disorders were not even known in February 2002 to be associated with the activity of JNK. The claims are not directed to a method of treatment but to the method of modulation of the JNK pathway, thus the applicants have not set forth the metes and bounds of the claim.

Claims 2, 3, 13-20, 23-26, 29-34 and 37-41 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

3. With regards to the provisional obviousness-type double patenting rejection of claims 1-3, 5, 6, 13-35 and 37-41 labeled paragraph 3 over copending Application No. 10/381,197 maintained in the last office action, the applicant's arguments have been fully considered but are not found persuasive. The applicant's stated that the claims of 10/381,197, is subject to a restriction requirement where the election was a piperidine ring and that the present claims are directed to a piperidino ring which are the same.

Claims 1-3, 5, 6, 13-35 and 37-41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No, 10/381,197, for reasons of record and stated above.

4. With regards to the provisional obviousness-type double patenting rejection of claims 1-3 and 5-26 labeled paragraph 4 over copending Application No. 10/381,200 of the last office action, the applicant's arguments have been fully considered but are not found persuasive. The applicant's stated that in 10/381,200, is currently under appeal, and it is not known what scope of claims will eventually be allowed and that it is premature to require a terminal disclaimer at this stage of the prosecution. Applicants are reminded that this is a provisional obviousness-type double patenting rejection, which is used when the other application is not patented yet.

Claims 1-3 and 5-41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No, 10/381,200, for reasons of record and stated above.

5. With regards to the provisional obviousness-type double patenting rejection of claims 1-3 and 5-26 labeled paragraph 5 over copending Application No. 10/381,665 of the last office action, the applicant's arguments have been fully considered but are not found persuasive. The applicant's stated that 10/381,665, has not yet been examined and that despite the provision in MPEP 804 that a provisional rejection can be addressed without waiting for the first patent to issue, this rejection can be repeated. Which is herein done so.

Claims 1-3 and 5-41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No, 10/381,665, for reasons of record and stated above.

6. The applicant's amendments and arguments are sufficient to overcome the 35 USC § 112, first paragraph rejection of claims 2, 3, 13-19, 23-26 and 29-41, labeled paragraph 7 maintained in the last office action, which is hereby **withdrawn**.

7. The applicant's amendments and arguments are sufficient to overcome the 35 USC § 112, second paragraph rejections of claims 2, 3, 9, 10, 27-31 and 36, labeled paragraph 8a), d), j), l) and q) maintained in the last office action, which are hereby **withdrawn**. However, with regards to the 35 USC § 112, second paragraph rejections of claims 10, 27, 28 and 36, labeled paragraph 8p) and s), the applicant's amendments and arguments have been fully considered, however they were not found persuasive.

p) The applicants' stated that Claim 10 has been amended to depend from claim 8 rather than claim 9, thus providing antecedent basis for H. However, there is no R⁶ in claim 8 or claim 1 from which claim 8 depends. Thus, there is insufficient antecedent basis for this limitation in the claim.

Claims 10 and 36 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

s) The applicants' stated that claims 27-31 have been amended to ensure that compound claims depend from compound claims and composition claims depend from composition claims. However, claims 27 and 28 have not been

amended and they still contain the recitation of compounds, i.e. the plural form of compound, which is indicative of a composition.

Claims 27 and 28 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

8. The applicant's amendments and arguments are sufficient to overcome the objection of claim 22, labeled paragraph 9 maintained in the last office action, which is hereby **withdrawn**.

9. With regards to the objection to the specification labeled paragraph 11 in the last office action the applicants were informed of the presence of an embedded hyperlink and/or other form of browser-executable code in the disclosure. The Applicant's requested clarification of the alleged hyperlink and/or other form of browser-executable code, which is found on page 26 line 10.

Appropriate correction is required.

10. The applicant's amendments and arguments are sufficient to overcome the 35 USC § 112, first paragraph rejection of claims 1, 3, 5-10, 20-22, 27-31 and 35-41, labeled paragraph 12 in the last office action, which is hereby **withdrawn**.

11. The applicant's amendments and arguments are sufficient to overcome the 35 USC § 112, first paragraph rejection of claims 5, 6 and 35, labeled paragraph 13 in the last office action, which is hereby **withdrawn**.

12. The applicant's amendments and arguments are sufficient to overcome the 35 USC § 112, second paragraph rejections of claims 1-3, 5-10 and 13-41, labeled paragraph 14b), d) and e) in the last office action, which are hereby **withdrawn**.

However, with regards to the 35 USC § 112, second paragraph rejections of claims 1-3, 5-10, 16-23, 27-31 and 35-41, labeled paragraph 14a), c) and f), the applicant's amendments and arguments have been fully considered, however they were not found persuasive.

a) The applicants' stated that "compounds" is not indefinite. Claim 1 defines a group of compounds having the formula as shown and that this formula embraces many compounds, each of which is described by differing substituents on the sulfonamide moiety. The applicants' also stated that it is respectfully submitted that the singular only applies when only one compound is claimed, not a family of compounds. However, formula I cannot be but one compound at a time so a "Sulfonamide compound according to formula I" is a single compound not a group of compounds. Additionally claims 3, 5-13, 16-21 and 35-37 are "A sulfonamide compound", i.e. singular.

Claims 1, 27, 28, 31 and 35-41 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and

distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

c) The applicants' stated that the final proviso that if X is oxygen, Y shall not be substituted by a group (C=O)N(R,R') at the α -position of the sulfonamide nitrogen because Y has been defined as a piperidino moiety. However, the rejection is such that at no time is Y substituted by (C=O)N(R,R').

Claims 1-3, 5-10, 20-22, 27-31 and 35-41 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

f) The applicants' stated that "compositions" is not indefinite and that more than one composition is covered by these claims. However, as stated above with respect to "compounds" formula I cannot be but one compound at a time so a "Sulfonamide compound according to formula I" is a single compound not a group of compounds. Additionally claims 2, 20 and 30 are a "composition", i.e. singular.

Claims 29 and 30 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

In view of the amendment dated March 30, 2006, the following new grounds of rejection apply:

Election/Restrictions

13. Claim 4 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 20, 2004.

Specification

14. The disclosure is objected to because of the following informalities:

The disclosure contains many formulas, which are not readable, **for example** page 9 none of the bonds are present.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 3, 9 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The definition of L¹ and L² wherein L¹ and L² is C₁-C₆-**aliphatic** alkyl is not described in the specification for the genus of formula I.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

16. Claims 2, 3, 5-7, 10, 13-15 and 30-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claims 2, 29 and 30 recite the limitation "a 4-8 membered saturated cyclic alkyl containing one or two nitrogen atoms" in the definition of Y in the first proviso. There is insufficient antecedent basis for this limitation in the claim.
- b) Claims 3 and 31 are vague and indefinite in that it is not known what is meant by aryl-C₁-C₆-alkyl in the definition of R³ and R^{3'}.
- c) Claims 3 and 31 are vague and indefinite in that it is not known what is meant by sulfonyl in the definition of R⁶.
- d) Claims 5-7 and 35 are vague and indefinite in that it is not known what is meant by sulfonyl in the definition of Ar¹ and Ar².
- e) Claim 10 and 36 are vague and indefinite in that it is not known what is meant by aryl-C₁-C₄-alkyl in the definition of R³.
- f) Claims 13-15 and 32-34 are vague and indefinite in that it is not known what is meant by unsubstituted aryl in the definition of Ar¹ and Ar².
- g) Claim 35 recites the limitation "C₁-C₄ alkyl group" in the second line of the claim. There is insufficient antecedent basis for this limitation in the claim.

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h) Claim 36 recites the limitation "a triazole ring which is fused with an unsubstituted or substituted aryl or heteroaryl" in the definition of L¹. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

17. Claims 1-3, 13-20, 23-27, 29, 31-33 and 37-41 are rejected under 35

U.S.C. 102(b) as being anticipated by JACOBS et al., U.S. Patent No. 6,399,603.

Jacobs teaches the compounds, compositions and method of use of the compounds of formula I where Y is piperidino, Ar² is 1,3-phenylene or 1,4-phenylene, n is 0 or 2, R¹ is H, X is O, Ar¹ is quinazoline substituted by nitro, hydroxyl, and 3,4-dichlorophenylamino. See examples 230, 324, 358, etc.

18. Claims 1-3 and 20 are rejected under 35 U.S.C. 102(a) as being anticipated by PINTO et al., U.S. Patent No. 6,020,357. Pinto teaches the compounds and compositions of the compounds of formula I where Y is piperidino, Ar² is 1,4-phenylene,

n is 0, R¹ is H, X is O, Ar¹ is pyrazole substituted by methyl and 3-(aminoiminomethyl)phenyl. See example 106 and claim 14, column 293, lines 14-15.

19. Claims 1-3, 5, 6, 13-18, 20, 24, 25, 32, 37, 39 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by CHANDRAKUMAR et al., U.S. Patent No. 5,843,906. Chandrakumar teaches the compounds, compositions and method of use of the compounds of formula I where Y is piperidino, R⁶ is -CH₂-COOH or -CH₂-COOEt, Ar² is 1,3-phenylene, n is 0, R¹ is H, X is O, Ar¹ is phenyl substituted by aminoiminomethylamino. See examples N and 6.


20. Claims 1, 3, 5, 6, 8, 9, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by GRIGORYAN et al., Armyanskii Khimicheskii Zhurnal. Grigoryan teaches the compounds of formula I where Y is piperidino, Ar² is 1,4-phenylene, n is 0, 1 or 2, R¹ is H, X is O, Ar¹ is phenyl substituted by ethoxy, propoxy or butoxy. See examples in the CAPLUS printout provided herewith.

21. Claims 1-3, 20 and 27-31 are rejected under 35 U.S.C. 102(b) as being anticipated by KALDRIKYAN et al., Khimiko-Farmatsevtricheskii Zhurnal. Kaldrikyan teaches the compounds, compositions and method of use of the compounds of formula I where Y is piperidino, Ar² is 1,4-phenylene, n is 1 or 2, R¹ is H, X is O, Ar¹ is benzofuran. See examples in the CAPLUS printout provided herewith.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Brenda L. Coleman
Primary Examiner Art Unit 1624
June 16, 2006